## Senate Study Bill 3117 - Introduced

SEN	ATE FILE
ВУ	(PROPOSED COMMITTEE ON
	HUMAN RESOURCES BILL BY
	CHAIRPERSON SWEENEY)

## A BILL FOR

- 1 An Act relating to continuity of care and nonmedical switching
- 2 by health carriers, health benefit plans, and utilization
- 3 review organizations, and including applicability
- 4 provisions.
- 5 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

- 1 Section 1. <u>NEW SECTION</u>. 514F.8 Continuity of care —
- 2 nonmedical switching.
- 3 l. Definitions. For the purpose of this section:
- 4 a. "Authorized representative" means the same as defined in
- 5 section 514J.102.
- 6 b. "Commissioner" means the commissioner of insurance.
- 7 c. "Cost sharing" means any coverage limit, copayment,
- 8 coinsurance, deductible, or other out-of-pocket expense
- 9 requirement.
- 10 d. "Coverage exemption" means a determination made by a
- 11 health carrier, health benefit plan, or utilization review
- 12 organization to cover a prescription drug that is otherwise
- 13 excluded from coverage.
- 14 e. "Coverage exemption determination" means a determination
- 15 made by a health carrier, health benefit plan, or utilization
- 16 review organization whether to cover a prescription drug that
- 17 is otherwise excluded from coverage.
- 18 f. "Covered person" means the same as defined in section
- 19 514J.102.
- 20 g. "Demonstrated bioavailability" means the same as defined
- 21 in section 155A.3.
- 22 h. "Discontinued health benefit plan" means a covered
- 23 person's existing health benefit plan that is discontinued by a
- 24 health carrier during open enrollment for the next plan year.
- 25 i. "Formulary" means a complete list of prescription drugs
- 26 eligible for coverage under a health benefit plan.
- 27 j. "Generic name" means the same as defined in section
- 28 155A.3.
- 29 k. "Health benefit plan" means the same as defined in
- 30 section 514J.102.
- 31 1. "Health care professional" means the same as defined in
- 32 section 514J.102.
- 33 m. "Health care services" means the same as defined in
- 34 section 514J.102.
- 35 n. "Health carrier" means the same as defined in section

- 1 514J.102.
- 2 o. "Interchangeable biological product" means the same as defined in section 155A.3.
- 4 p. "Nonmedical switching" means a health benefit plan's
- 5 restrictive changes to the health benefit plan's formulary
- 6 after the current plan year has begun or during the open
- 7 enrollment period for the upcoming plan year, causing a covered
- 8 person who is medically stable on the covered person's current
- 9 prescribed drug as determined by the prescribing health care
- 10 professional, to switch to a less costly alternate prescription 11 drug.
- 12 q. "Open enrollment" means the yearly time period an
- 13 individual can enroll in a health benefit plan.
- 14 r. "Utilization review" means the same as defined in 514F.7.
- 15 s. "Utilization review organization" means the same as
- 16 defined in 514F.7.
- 2. Nonmedical switching. With respect to a health carrier
- 18 that has entered into a health benefit plan with a covered
- 19 person that covers prescription drug benefits, all of the
- 20 following apply:
- 21 a. A health carrier, health benefit plan, or utilization
- 22 review organization shall not limit or exclude coverage of
- 23 a prescription drug for any covered person who is medically
- 24 stable on such drug as determined by the prescribing health
- 25 care professional, if all of the following apply:
- 26 (1) The prescription drug was previously approved by the
- 27 health carrier for coverage for the covered person.
- 28 (2) The covered person's prescribing health care
- 29 professional has prescribed the drug for the medical condition
- 30 within the previous six months.
- 31 (3) The covered person continues to be an enrollee of the
- 32 health benefit plan.
- 33 b. Coverage of a covered person's prescription drug, as
- 34 described in paragraph "a", shall continue through the last day
- 35 of the covered person's eligibility under the health benefit

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- 1 plan, inclusive of any open enrollment period.
- 2 c. Prohibited limitations and exclusions referred to in
- 3 paragraph a include but are not limited to the following:
- 4 (1) Limiting or reducing the maximum coverage of
- 5 prescription drug benefits.
- 6 (2) Increasing cost sharing for a covered prescription
  7 drug.
- 8 (3) Moving a prescription drug to a more restrictive tier if 9 the health carrier uses a formulary with tiers.
- 10 (4) Removing a prescription drug from a formulary, unless
- 11 the United States food and drug administration has issued a
- 12 statement about the drug that calls into question the clinical
- 13 safety of the drug, or the manufacturer of the drug has
- 14 notified the United States food and drug administration of a
- 15 manufacturing discontinuance or potential discontinuance of the
- 16 drug as required by section 506C of the Federal Food, Drug, and
- 17 Cosmetic Act, as codified in 21 U.S.C. §356c.
- 18 d. A drug product with the same generic name and
- 19 demonstrated bioavailability, or an interchangeable biological
- 20 product, shall be considered equivalent to the prescription
- 21 drug prescribed by the covered person's health care
- 22 professional.
- 3. Coverage exemption determination process.
- 24 a. To ensure continuity of care, a health carrier, health
- 25 plan, or utilization review organization shall provide a
- 26 covered person and prescribing health care professional with
- 27 access to a clear and convenient process to request a coverage
- 28 exemption determination. A health carrier, health plan, or
- 29 utilization review organization may use its existing medical
- 30 exceptions process to satisfy this requirement. The process
- 31 used shall be easily accessible on the internet site of the
- 32 health carrier, health benefit plan, or utilization review
- 33 organization.
- 34 b. A health carrier, health benefit plan, or utilization
- 35 review organization shall respond to a coverage exemption

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- 1 determination request within seventy-two hours of receipt. Ir
- 2 cases where exigent circumstances exist, a health carrier,
- 3 health benefit plan, or utilization review organization shall
- 4 respond within twenty-four hours of receipt. If a response by
- 5 a health carrier, health benefit plan, or utilization review
- 6 organization is not received within the applicable time period,
- 7 the coverage exemption shall be deemed granted.
- 8 c. A coverage exemption shall be expeditiously granted for a
- 9 discontinued health benefit plan if a covered person enrolls in
- 10 a comparable plan offered by the same health carrier, and all
- 11 of the following conditions apply:
- 12 (1) The covered person is medically stable on a prescription
- 13 drug as determined by the prescribing health care professional.
- 14 (2) The prescribing health care professional continues
- 15 to prescribe the drug for the covered person for the medical  $\ensuremath{\mathsf{T}}$
- 16 condition.
- 17 (3) In comparison to the discontinued health benefit plan,
- 18 the new health benefit plan does any of the following:
- 19 (a) Limits or reduces the maximum coverage of prescription
- 20 drug benefits.
- 21 (b) Increases cost sharing for the prescription drug.
- 22 (c) Moves the prescription drug to a more restrictive tier
- 23 if the health carrier uses a formulary with tiers.
- 24 (d) Excludes the prescription drug from the formulary.
- 25 d. Upon granting of a coverage exemption for a drug
- 26 prescribed by a covered person's prescribing health care
- 27 professional, a health carrier, health benefit plan, or
- 28 utilization review organization shall authorize coverage no
- 29 more restrictive than that offered in a discontinued health
- 30 benefit plan, or than that offered prior to implementation of
- 31 restrictive changes to the health benefit plan's formulary
- 32 after the current plan year began.
- e. If a determination is made to deny a request for a
- 34 coverage exemption, the health carrier, health benefit plan,
- 35 or utilization review organization shall provide the covered

1 person or the covered person's authorized representative and

- 2 the authorized person's prescribing health care professional
- 3 with the reason for denial and information regarding the
- 4 procedure to appeal the denial. Any determination to deny a
- 5 coverage exemption may be appealed by a covered person or the
- 6 covered person's authorized representative.
- 7 f. A health carrier, health benefit plan, or utilization
- 8 review organization shall uphold or reverse a determination to
- 9 deny a coverage exemption within seventy-two hours of receipt
- 10 of an appeal of denial. In cases where exigent circumstances
- ll exist, a health carrier, health benefit plan, or utilization
- 12 review organization shall uphold or reverse a determination to
- 13 deny a coverage exemption within twenty-four hours of receipt.
- 14 If the determination to deny a coverage exemption is not upheld
- 15 or reversed on appeal within the applicable time period, the
- 16 denial shall be deemed reversed and the coverage exemption
- 17 shall be deemed approved.
- 18 q. If a determination to deny a coverage exemption is
- 19 upheld on appeal, the health carrier, health benefit plan,
- 20 or utilization review organization shall provide the covered
- 21 person or covered person's authorized representative and the
- 22 covered person's prescribing health care professional with
- 23 the reason for upholding the denial on appeal and information
- 24 regarding the procedure to request external review of the
- 25 denial pursuant to chapter 514J. Any denial of a request for a
- 26 coverage exemption that is upheld on appeal shall be considered
- 27 a final adverse determination for purposes of chapter 514J and
- 28 is eligible for a request for external review by a covered
- 29 person or the covered person's authorized representative
- 30 pursuant to chapter 514J.
- 31 4. Limitations. This section shall not be construed to do
- 32 any of the following:
- 33 a. Prevent a health care professional from prescribing
- 34 another drug covered by the health carrier that the health care
- 35 professional deems medically necessary for the covered person.

- 1 b. Prevent a health carrier from doing any of the following:
- 2 (1) Adding a prescription drug to its formulary.
- 3 (2) Removing a prescription drug from its formulary if the
- 4 drug manufacturer has removed the drug for sale in the United
- 5 States.

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- 6 5. Enforcement. The commissioner may take any enforcement
- 7 action under the commissioner's authority to enforce compliance
- 8 with this section.
- 9 Sec. 2. APPLICABILITY. This Act applies to a health benefit
- 10 plan that is delivered, issued for delivery, continued, or
- 11 renewed in this state on or after January 1, 2021.
- 12 EXPLANATION
- The inclusion of this explanation does not constitute agreement with the explanation's substance by the members of the general assembly.

- 16 person and nonmedical switching by health carriers, health
- 17 benefit plans, and utilization review organizations.
- 18 The bill defines "nonmedical switching" as a health benefit

This bill relates to the continuity of care for a covered

- 19 plan's restrictive changes to the health benefit plan's
- 20 formulary after the current plan year has begun or during the
- 21 open enrollment period for the upcoming plan year, causing a
- 22 covered person who is medically stable on the covered person's
- 23 current prescribed drug as determined by the prescribing
- 24 health care professional, to switch to a less costly alternate
- 25 prescription drug.
- 26 The bill provides that during a covered person's eligibility
- 27 under a health benefit plan, inclusive of any open enrollment
- 28 period, a health plan carrier, health benefit plan, or
- 29 utilization review organization shall not limit or exclude
- 30 coverage of a prescription drug for the covered person if the
- 31 covered person is medically stable on the drug as determined
- 32 by the prescribing health care professional, the drug was
- 33 previously approved by the health carrier for coverage for the
- 34 person, and the person's prescribing health care professional
- 35 has prescribed the drug for the covered person's medical

- 1 condition within the previous six months. The bill includes,
- 2 as prohibited limitations or exclusions, reducing the maximum
- 3 coverage of prescription drug benefits, increasing cost sharing
- 4 for a covered drug, moving a drug to a more restrictive tier,
- 5 and removing a drug from a formulary. A prescription drug
- 6 may, however, be removed from a formulary if the United States
- 7 food and drug administration issues a statement regarding the
- 8 clinical safety of the drug, or the manufacturer of the drug
- 9 notifies the United States food and drug administration of a
- 10 manufacturing discontinuance or potential discontinuance of the
- 11 drug as required by section 506c of the Federal Food, Drug,
- 12 and Cosmetic Act. The bill provides that a drug product with
- 13 the same generic name and demonstrated bioavailability, or an
- 14 interchangeable biological product, is considered equivalent to
- 15 the prescription drug prescribed by the covered person's health
- 16 care professional.
- 17 The bill requires a covered person and prescribing health
- 18 care professional to have access to a process to request a
- 19 coverage exemption determination. The bill defines "coverage
- 20 exemption determination" as a determination made by a
- 21 health carrier, health benefit plan, or utilization review
- 22 organization whether to cover a prescription drug that is
- 23 otherwise excluded from coverage.
- 24 A coverage exemption determination request must be approved
- 25 or denied by the health carrier, health benefit plan, or
- 26 utilization review organization within 72 hours, or within 24
- 27 hours if exigent circumstances exist. If a determination is
- 28 not received within the applicable time period the coverage
- 29 exemption is deemed granted.
- 30 The bill requires a coverage exemption to be expeditiously
- 31 granted for a health benefit plan discontinued for the next
- 32 plan year if a covered person enrolls in a comparable plan
- 33 offered by the same health carrier, and in comparison to the
- 34 discontinued health benefit plan, the new health benefit plan
- 35 limits or reduces the maximum coverage for a prescription drug,

- 1 increases cost sharing for the prescription drug, moves the
- 2 prescription drug to a more restrictive tier, or excludes the
- 3 prescription drug from the formulary.
- 4 If a coverage exemption is granted, the bill requires an
- 5 authorization of coverage that is no more restrictive than that
- 6 offered in a discontinued health benefit plan, or than that
- 7 offered prior to implementation of restrictive changes to the
- 8 health benefit plan's formulary after the current plan year
- 9 began.
- 10 If a determination is made to deny a request for a
- 11 coverage exemption, the reason for denial and the procedure
- 12 to appeal the denial must be provided to the requestor. Any
- 13 determination to deny a coverage exemption may be appealed to
- 14 the health carrier, health benefit plan, or utilization review
- 15 organization.
- 16 A determination to uphold or reverse denial of a coverage
- 17 exemption must be made within 72 hours of receipt of an appeal,
- 18 or within 24 hours if exigent circumstances exist. If a
- 19 determination is not made within the applicable time period,
- 20 the denial is deemed reversed and the coverage exemption is
- 21 deemed approved.
- 22 If a determination to deny a coverage exemption is upheld on
- 23 appeal, the reason for upholding the denial and the procedure
- 24 to request external review of the denial pursuant to Code
- 25 chapter 514J must be provided to the individual who filed the
- 26 appeal. Any denial of a request for a coverage exemption that
- 27 is upheld on appeal is considered a final adverse determination
- 28 for purposes of Code chapter 514J and is eligible for a request
- 29 for external review by a covered person or the covered person's
- 30 authorized representative pursuant to Code chapter 514J.
- 31 The bill shall not be construed to prevent a health care
- 32 professional from prescribing another drug covered by the
- 33 health carrier that the health care professional deems
- 34 medically necessary for the covered person.
- 35 The bill shall not be construed to prevent a health carrier

- 1 from adding a drug to its formulary or removing a drug from its
- 2 formulary if the drug manufacturer removes the drug for sale in
- 3 the United States.
- 4 The bill allows the commissioner to take any necessary
- 5 enforcement action under the commissioner's authority to
- 6 enforce compliance with the bill.
- 7 The bill is applicable to health benefit plans that are
- 8 delivered, issued for delivery, continued, or renewed in this
- 9 state on or after January 1, 2021.